



U.S. Department of Justice

United States Attorney
District of New Jersey

CRAIG CARPENITO
UNITED STATES ATTORNEY

Nicole F. Mastropieri
Assistant United States Attorney

970 Broad Street, Suite 700
Newark, NJ 07102
nicole.mastropieri@usdoj.gov

main: (973) 645-2700
direct: (973) 645-6548

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Via E-Mail

The Honorable Dennis M. Cavanaugh
Special Master
McElroy, Deutsch, Mulvaney & Carpenter LLP
1300 Mount Kemble Ave
P.O. Box 2075
Morristown, NJ 07962-2075
DCAVANAUGH@MDMC-LAW.com

Re: *United States ex rel. Simpson v. Bayer Pharmaceutical Corp., et al.*
Civil Action No. 2:05-cv-03895 (JMZ) (JAD)

Dear Judge Cavanaugh:

The United States respectfully submits this Reply letter brief in support of its motion to quash or modify a third-party subpoena that defendant Bayer Corporation (Bayer) served on the Centers for Medicare and Medicaid Services (CMS).

Even though it bears the burden of demonstrating relevance, in its Letter Response to the Government's motion to quash (Bayer Resp.), Bayer does not even attempt to demonstrate the relevance of the aged paper records to the materiality inquiry, much less address the Government's arguments that the aged paper records are demonstrably irrelevant. Nor does Bayer even attempt to explain how 275,000 boxes of aged paper records, consisting of 687 million pages, is proportional to the needs of the case under Fed. R. Civ. P. 26(b)(1).

Instead, Bayer makes a series of arguments that are incorrect and designed to improperly shift the burden to the Government to solve a problem that Bayer created and seems unwilling to address. Bayer's assertion that the Government does not know the contents of the boxes and has not even looked at the manifests is belied by the initial and supplemental declarations of Chris Klots. *See* ECF Nos. 363-1, 366-1. Bayer's claim that counsel for CMS "confirmed" on the phone that "CMS has never denied payment based on non-compliance with the laws at issue" is false. Not only did counsel for CMS repeatedly decline to make such a representation but such a representation would be inaccurate, impossible to verify, and meaningless. Finally, Bayer's contention that the Government rejected Bayer's offer to review a sample omits the critical fact

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that, prior to filing its motion to quash, the Government repeatedly offered Bayer that option so that Bayer could see for itself that the aged paper records were irrelevant. It was only after Bayer declined that offer that the Government had no choice but to file the motion to quash.

In light of the undisputed burdens and disruptions to CMS caused by the unprecedented scope of the subpoena and Bayer's complete failure to satisfy its burden of demonstrating relevance and proportionality, the United States respectfully requests that the Court grant its motion to quash or modify Bayer's subpoena to exclude the years 1996 through 1999.

1. Bayer Has Failed to Meet its Burden of Demonstrating Relevance and Proportionality.

As expressly noted by Judge Cavanaugh when resolving a prior discovery dispute in this case, "the burden remains on the party seeking discovery to 'show that the information sought is relevant to the subject matter of the action and may lead to admissible evidence.'" See ECF No. 342, Order and Opinion of the Special Master at 2 (D.N.J. Mar. 5, 2019) (quoting *Caver v. City of Trenton*, 192 F.R.D. 154, 159 (D.N.J. 2000)). Furthermore, "courts will not permit parties to engage in fishing expeditions." *Id.* In this case Bayer has completely failed to meet its burden of demonstrating relevance and proportionality.

As explained in the Government's Letter Brief, the aged paper records from 1996 through 1999 are irrelevant because they have no bearing on the materiality inquiry under *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (*Escobar*) and this Court's April 23, 2019 decision. See *United States ex rel. Simpson v. Bayer*, 376 F. Supp. 3d 392 (D.N.J. 2019).

The materiality inquiry under *Escobar* examines whether non-compliance with a statute or other requirement is capable of influencing the agency's payment decision. As the Court explained, there are various ways to assess materiality, including what the Government does when it learns about non-compliance. It is a holistic inquiry into whether a non-compliance with a particular statute or requirement actually matters.

One of the violations at issue in this case concerns the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b. Given the unique importance of the AKS to federal healthcare programs, the widespread acknowledgement by courts that compliance with the AKS affects federal health care reimbursement decisions, and Congress' determination that claims resulting from kickbacks are false,¹ courts have held that violations of the AKS are material under the FCA *as a matter of law*. See, e.g., *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 818 (S.D.N.Y. 2017), *rev'd and remanded on other grounds*,

¹ In the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, 757 (2010), Congress made clear that a claim to a federal health care program that violates the AKS is per se a false or fraudulent claim under the FCA. See 42 U.S.C. § 1320a-7b(g) ("In addition to the penalties provided for in this section . . . , a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."); *United States ex rel. Greenfield v. Medco Health Solutions*, 880 F.3d 89, 95 (3d Cir. 2018).

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899 F.3d 163 (2d Cir. 2018). The other violation at issue concerns the Medicare statute's "reasonable and necessary" requirement. *See* 42 U.S.C. § 1396y(a)(1)(A). This provision, which is arguably at the core of all coverage determinations, is of obvious importance as this Court has recognized it as a "condition of payment." *See Bayer* 376 F. Supp. 3d at 414.

Bayer has not offered any credible argument or explanation as to how the aged paper records would contradict these bedrock principles. Indeed, it is hard to imagine what Bayer hopes to glean from those records that would bear on the common sense inquiry into the materiality of the AKS and "reasonable and necessary" requirement.

Moreover, as the Government explained in its Letter Brief, to the extent government action plays any role in evaluating materiality, the inquiry concerns those instances when the Government pays claims with "*actual knowledge* that certain requirements were violated[.]" *See Bayer*, 376 F. Supp. 3d at 415.

As a practical matter, there is virtually no way that the aged paper records from 1996 through 1999 are relevant to the government action factor because they largely predate the relevant time period in the case,² concern Medicare claims other than those involving Trasylol or Avelox,³ and could not possibly contain evidence of "actual knowledge" of the violations alleged in the relator's complaint. Perhaps recognizing its inability to demonstrate actual relevance, Bayer contends that the aged paper records "are at least potentially relevant under Judge Linares's ruling, which focus[es] on the Government's 'payment of claims.'" Bayer Resp. at 7. But Bayer has offered no explanation as to how "as submitted" paper claims, which do not actually contain the payment decisions, *see* Klots Decl. ¶ 14, could possibly shed light on "what the Government would have done *had it known* about the alleged noncompliance involving Trasylol" or Avelox. *See Bayer*, 376 F. Supp. 3d at 414 (emphasis in original).⁴ Bayer's

² In its responses to the Relator's requests for production of documents in this case, Bayer defined the "Relevant Time Period" with regard to Trasylol as August 5, 1999 to November 5, 2007, and with regard to Avelox as July 24, 2000 to December 31, 2004. *See* Defendant's Response to Plaintiff's Second Request for Production at 5 (attached as Exhibit 1). In fact Bayer objected to producing documents outside the "Relevant Time Period" as "overly broad" and "unduly burdensome." *See* Defendant's Response to Relator's Third Request for Production at 4-5 (attached as Exhibit 2).

³ Bayer's argument that analysis of the "mine run of cases" is not limited to claims involving Trasylol or Avelox misreads the district court's April 23, 2019 decision in this case. In its decision, the district court stated that "[b]eyond this important factor, Relator must provide '**evidence that [Bayer] knows** that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with' the AKS or the reasonable and necessary requirement as it relates to off-label cases." The evidence identified by the Court is **Bayer's knowledge** of the Government's payment practices. Furthermore, in *Escobar* itself, the Supreme Court explained that such evidence is not dispositive, declaring that "proof of **materiality can include, but is not necessarily limited to**, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases. . ." *Escobar*, 136 S. Ct. at 2003-04 (emphasis added).

⁴ Bayer also fails to explain how any of the non-claim paper records, such as overpayment case files, provider enrollment records, Medicare program financial files, or other administrative documents have any bearing on the materiality question under *Escobar*.

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reliance on “potential relevance” only underscores its inability to demonstrate the actual relevance of the aged paper records.

Bayer has not even attempted to argue that the demands of its subpoena are proportional to the needs of the case. Bayer does not dispute that the costs to review 275,000 boxes could easily consume 1.3 million labor hours, exceed \$70 million, and take several years to complete. *See* Klots Supp. Decl. ¶ 5. Nor does Bayer contest that its subpoena has forced the agency to incur \$37,000 in unnecessary additional storage costs each month with this cost rising to \$70,000 per month by the end of May 2020. *See* Klots Supp. Decl. ¶ 9. Bayer does not dispute that its subpoena has been extremely disruptive to CMS, forcing the halt of its pre-planned disposal program, requiring unscheduled contract modifications, the reprogramming of millions of dollars in allocated funds, and resulting in the loss of appropriated funds. In short, Bayer cannot dispute that its subpoena to CMS, covering a 23 year period, is overly broad, unduly burdensome, and oppressive.

If Bayer was genuinely interested in “the Government’s payment of claims,” there is a less burdensome, less expensive, and better alternative to the “as submitted” paper claims. CMS has offered to produce to Bayer electronic claims data in response to an appropriately framed and narrowly targeted data request. CMS received a request from Relator’s counsel for electronic claims data and invited Bayer’s counsel to collaborate on that request, but Bayer declined to do so. Instead, Bayer continues to demand that the Government retain—indefinitely—hundreds of millions of “as submitted” paper claims that lack payment decisions, fall largely outside the relevant time period, are unrelated to Trasyolol or Avelox, and Bayer itself appears to have no interest in actually reviewing. Bayer’s facially overbroad subpoena thus amounts to an impermissible and disproportionate “fishing expedition” for irrelevant documents.

2. CMS Cannot Agree to Bayer’s Proposed Stipulation Because it is Inaccurate.

The Government wishes to address Bayer’s refusal to narrow its subpoena unless the Government enters into a stipulation that it has “never denied payment based upon non-compliance with the laws at issue.” Bayer Resp. at 10.⁵ There are several problems with Bayer’s approach, which seeks to extract from the Government an inaccurate stipulation or be forced to comply with Bayer’s facially overbroad and unduly burdensome discovery.

Contrary to Bayer’s statement at page 10 of its Response, at no time has “the agency confirmed on the phone” that “CMS has never denied payment based on non-compliance with the law at issue.” Bayer’s statement is false and contradicted by its own August 23, 2019 letter, in which Bayer’s counsel acknowledged that CMS has “not agreed to the stipulation[.]” CMS

⁵ Counsel for CMS repeatedly advised Bayer that if it sought a specific representation from CMS it should follow the Department’s *Touhy* regulations, which it has failed to do thus far.

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has not since changed its position.⁶ Counsel for CMS repeatedly advised Bayer that any representation that “CMS has never denied payment” was not possible.

Such a broad and unequivocal statement about every claim ever processed by Medicare is inaccurate and impossible to verify. CMS processes hundreds of millions of Medicare Part A and Part B claims each year through automated processing systems. CMS denies claims routinely and for a variety of reasons, including, for example, because an item or service is not “reasonable and necessary.” The Government routinely takes action to recover overpayments, whether resulting from errors or fraud. However, CMS rarely, if ever, has “actual knowledge” of kickback violations at the time of payment. It is highly unlikely that an entity paying a kickback would admit to its violation of the AKS on the face of the claim. Judge Linares recognized this point when noting that “all fraud is disguised –until it is not.” *Bayer*, 376 F. Supp. 3d at 416. As a result, the Government frequently pursues False Claims Act cases arising from the violations at issue in this case to recover the funds after the fact. Thus, in addition to being inaccurate, Bayer’s stipulation would be meaningless.

Bayer presents the government with a false choice between entering into what the government believes is an inaccurate and irrelevant stipulation or complying with facially overbroad and unduly burdensome discovery demands for hundreds of millions of pages of irrelevant documents. Bayer has an independent and mandatory duty under Rule 45(d)(1) to ensure that its discovery requests do not impose undue burden and expense on the United States, a non-party in this declined action.⁷ Disregarding this mandatory duty, Bayer has instead attempted to leverage its overly broad and unduly burdensome discovery to secure a litigation advantage in this case.

As for Bayer’s new-found willingness to review a sample of the aged paper records, this option will only prolong the resolution of a situation that is imposing substantial burdens and disruptions on the agency. As previously noted, the aged paper records were part of a pre-planned disposal of aged paper records, which has come to a halt solely because of Bayer’s subpoena. *See* Klots Supp. Decl. ¶ 9. As a result, CMS has been forced to undertake unplanned contract modifications, reprogram millions of dollars of funds allocated for disposal costs, and suffer the loss of appropriated funds. *See* Klots Decl. ¶¶ 33-36, 38. *Cf. Trump v. Sierra Club*, 140 S. Ct. 1 (2019) (Breyer, J. concurring in part and dissenting in part) (suggesting that the

⁶ Having rejected such broad and unequivocal language, at Bayer’s request, counsel for CMS attempted in good faith to come up with alternate language for discussion purposes. Counsel for CMS repeatedly advised Bayer, however, that any language would ultimately have to be formally approved by the Administrator or her designee pursuant to the Department’s *Touhy* regulations. Ultimately, based on Bayer’s negotiating posture, counsel for CMS concluded that Bayer was unlikely to narrow its subpoena.

⁷ Bayer erroneously argues that *United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2008) is inapplicable because “*Eisenstein* made no mention of discovery.” Bayer Resp. at 10. On the contrary, the Supreme Court expressly identified party discovery under Rules 26(a), 34, and 37 as one of the “burdens attendant to full party status.” *Eisenstein*, 556 U.S. at 934. In *Eisenstein*, the Supreme Court held that when the United States declines to intervene under the FCA, it declines to assume the burdens attendant to full party status, which includes party discovery. Bayer itself recognized the non-party status of the United States in this declined action by serving its subpoena pursuant to Fed. R. Civ. P. 45.

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Government may be irreparably harmed if it is unable finalize contracts and loses appropriated funds). In light of these documented and uncontested harms to the agency, Bayer's suggestion that "the dispute is saving taxpayer's money" is absurd on its face. *See* Bayer Resp. at 9. More importantly, Bayer's belated willingness to review a sample does nothing to narrow the scope of the subpoena, remove any of the burdens identified above, or lessen the Government's urgent need for relief. Rather, it only serves a strategy of delay.

Bayer's unexplained refusal to review a sample prior to the motion to quash suggests that Bayer knew that the aged paper records are irrelevant to this case. A speedy review of a sample prior to the motion would have required Bayer to admit that the aged paper records have no probative value and would have removed Bayer's leverage – to coerce from the Government either a dismissal of relator's claims pursuant to 31 U.S.C. § 3730(c)(2)(A) or an inaccurate and irrelevant stipulation.

3. The Klots Declaration Describes in Detail the Content of the Documents.

Bayer argues that the Government does not know what is in the aged paper boxes, has not reviewed the manifests, and cannot therefore take a position on relevance. *See* Bayer Resp. at 6. Contrary to Bayer's argument, however, the initial and supplemental declarations of Chris Klots describe in detail the types of documents contained within aged paper records and the basis for Mr. Klots knowledge. *See* Klots Decl. ¶ 14 (describing that the vast majority of the Aged Paper Records consist of "as submitted" Medicare Part A and Part B paper claims that do not contain the final administrative action taken on the claim); *see also* Supp. Klots Decl. ¶ 6; Klots Decl. ¶ 18 (describing in detail the additional categories of Part A and Part B paper records); *see id.* ¶ 15 (describing the declarant's basis for his personal knowledge of the categories of paper records contained with the aged paper boxes); ¶ 16 (describing the declarant's personal review of manifests associated with the boxes of aged paper records); ¶ 17 (describing the results of the declarant's electronic searches of the manifests for the words Trasylol or Avelox). Bayer has not contradicted the Klots Declarations in any way.

In sum, Bayer's inability to demonstrate the relevance and proportionality of its vastly overbroad and unduly burdensome subpoena, combined with its refusal to narrow its scope or accept less burdensome alternatives, make it abundantly clear that its subpoena is not designed to elicit relevant information proportional to the needs of the case. Its refusal to take the opportunity to review for itself a sample prior to the Government's filing of its motion to quash, only serves to underscore what Bayer likely already knows – that the aged paper records are irrelevant. To the extent Bayer's subpoena is intended to create burden and expense on the Government in the hopes of obtaining a dismissal of relator's claims or an inaccurate stipulation for its own litigation advantage, that is an illegitimate basis for discovery and should not be countenanced by this Court. The United States respectfully requests that the Court grant its motion to quash or modify its subpoena to exclude the years 1996 through 1999.

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Respectfully submitted,

By: /s/ Nicole F. Mastropieri

NICOLE F. MASTROPIERI

Assistant United States Attorney

Attorneys for the United States

ANDY MAO

JAMIE YAVELBERG

SANJAY M. BHAMBHANI

Civil Division

Commercial Litigation Branch

P.O. Box 261, Ben Franklin Station

Washington, D.C. 20044

(202) 305-0546

Attorneys for the United States

cc: All Counsel of Record (via email)